

In 09/534,960

Serial No. 09/534,960

Part 03
#18

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PATENT TRADEMARK OFFICE

Docket No: 3940/OK188

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Michael Friedman et al.

Serial No.: 09/534,960

Art Unit: 1615

Confirmation No.: 3862

Filed: March 27, 2000

Examiner: S. Lee Howard

For: CONTROLLED DELIVERY SYSTEM OF ANTIFUNGAL AND KERATOLYTIC AGENTS FOR LOCAL TREATMENT OF FUNGAL INFECTIONS OF THE NAIL AND SURROUNDING TISSUES

UNOFFICIAL COMMUNICATION

(proposed)

Hon. Commissioner of
Patents and Trademarks
Washington, DC 20231

November 21, 2002

Please find the proposed claim amendments below.

47. (Amended) A sustained release therapeutic nail varnish composition comprising:

- (a) an antifungal effective amount of an antifungal agent;
- ✓(b) a keratolytic agent in an amount sufficient to increase permeability of the nail;
- ✓(c) greater than 3% (w/w) of a humectant to trap water;
- ✓(d) water in an amount sufficient to hydrate the nail and thereby to increase permeability of the nail in combination with said keratolytic agent;
- (e) a polymeric film forming agent; and
- (f) a volatile solvent; said film forming agent being selected so as to form a sustained release film upon application of said composition on a nail and evaporation of said volatile solvent, said film configured to trap water from said composition and maintain it in contact with said nail, said water and said humectant in combination facilitating penetration of said antifungal agent into the nail, and thereby enhancing therapeutic effectiveness of said antifungal agent.

Support at: p.20, lines 5-7; p.20, lines 11-12; p.22, lines 10-12; p.22, lines 12-14; p.23, lines 12-13; and p.19, lines 7-17.

96. (Amended) A sustained release therapeutic nail varnish composition comprising:

- (a) an antifungal effective amount of an antifungal agent;
- (b) a keratolytic agent in an amount sufficient to increase permeability of the nail;
- (c) a humectant to trap water;
- (d) a polymeric film forming agent;
- (e) water; and
- (f) a volatile solvent; wherein upon application on a nail, the volatile solvent evaporates and a film coating forms on the surface of the nail, the film coating releasing the antifungal and keratolytic agents in [therapeutic

levels] effective amounts over a prolonged period of time and trapping water in contact with the nail; the humectant retaining [the] water in the film; and said keratolytic agent and said water increasing permeability of the nail surface and facilitating penetration of the released antifungal agent [beyond] below the nail surface.

Support at: p.20, lines 5-7; p.20, lines 11-12; p.22, lines 10-12; p.22, lines 12-14; p.23, lines 12-13; and p.19, lines 7-17.

98. (New) A method of treating a fungal infection comprising the administration of a therapeutically effective amount of a sustained release therapeutic nail varnish composition, wherein the composition comprises:

- (a) an antifungal effective amount of an antifungal agent;
- (b) a keratolytic agent in an amount sufficient to increase permeability of the nail;
- (c) greater than 3% (w/w) of a humectant to trap water;
- (d) water in an amount sufficient to hydrate the nail and thereby to increase permeability of the nail in combination with said keratolytic agent;
- (e) a polymeric film forming agent; and
- (f) a volatile solvent; said film forming agent being selected so as to form a sustained release film upon application of said composition on a nail and evaporation of said volatile solvent, said film configured to trap water from said composition and maintain it in contact with said nail, said water and said humectant in combination facilitating penetration of said antifungal agent into the nail, and thereby enhancing therapeutic effectiveness of said antifungal agent.

Support at: p.17, line 17-p.18, line 2; p.18, lines 12-14; p.20, lines 5-7; p.20, lines 11-12; p.22, lines 10-12; p.22, lines 12-14; p.23, lines 12-13; and p.19, lines 7-17.